M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: April 8, 1999

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To: Dockets Management Branch (HFA-305)

From: Ted Sherwood
Management Analyst
Office of Generic Drugs

Subject: Presentation Regarding Human Generic Drugs to Docket 90S-0308

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Issues and Challenges for the Year Ahead

Presented for: GPIA 1999 Annual Meeting

Date Presented: March 26, 1999

Presented by: Douglas L. Sporn

Number of Pages: 13

Ted Sherwood

Attachment

90S-0308

M636

196

GPIA 1999 Annual Meeting

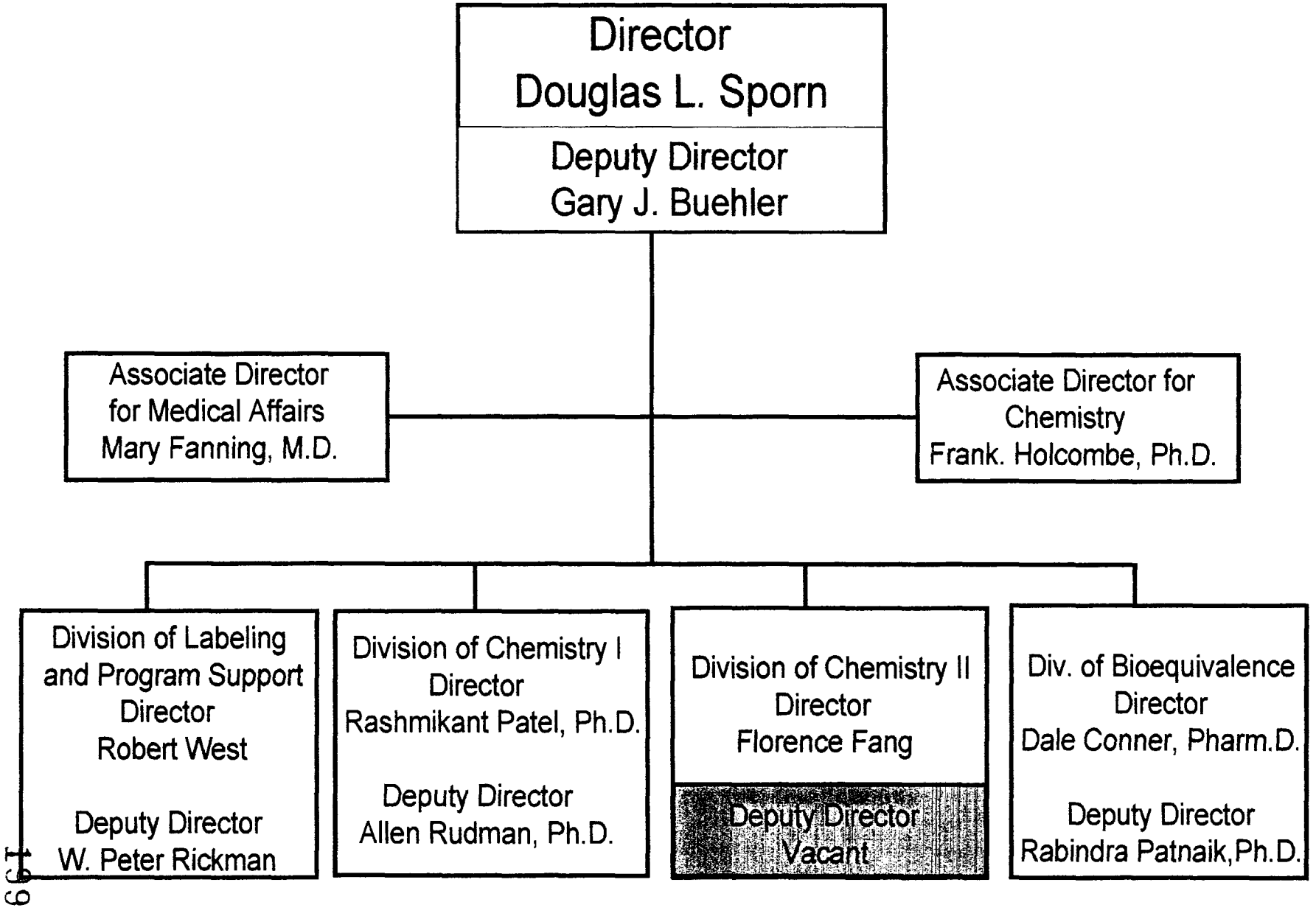
Issues and Challenges for the Year Ahead

Douglas L. Sporn
Director
Office of Generic Drugs
March 26, 1999
New York, NY

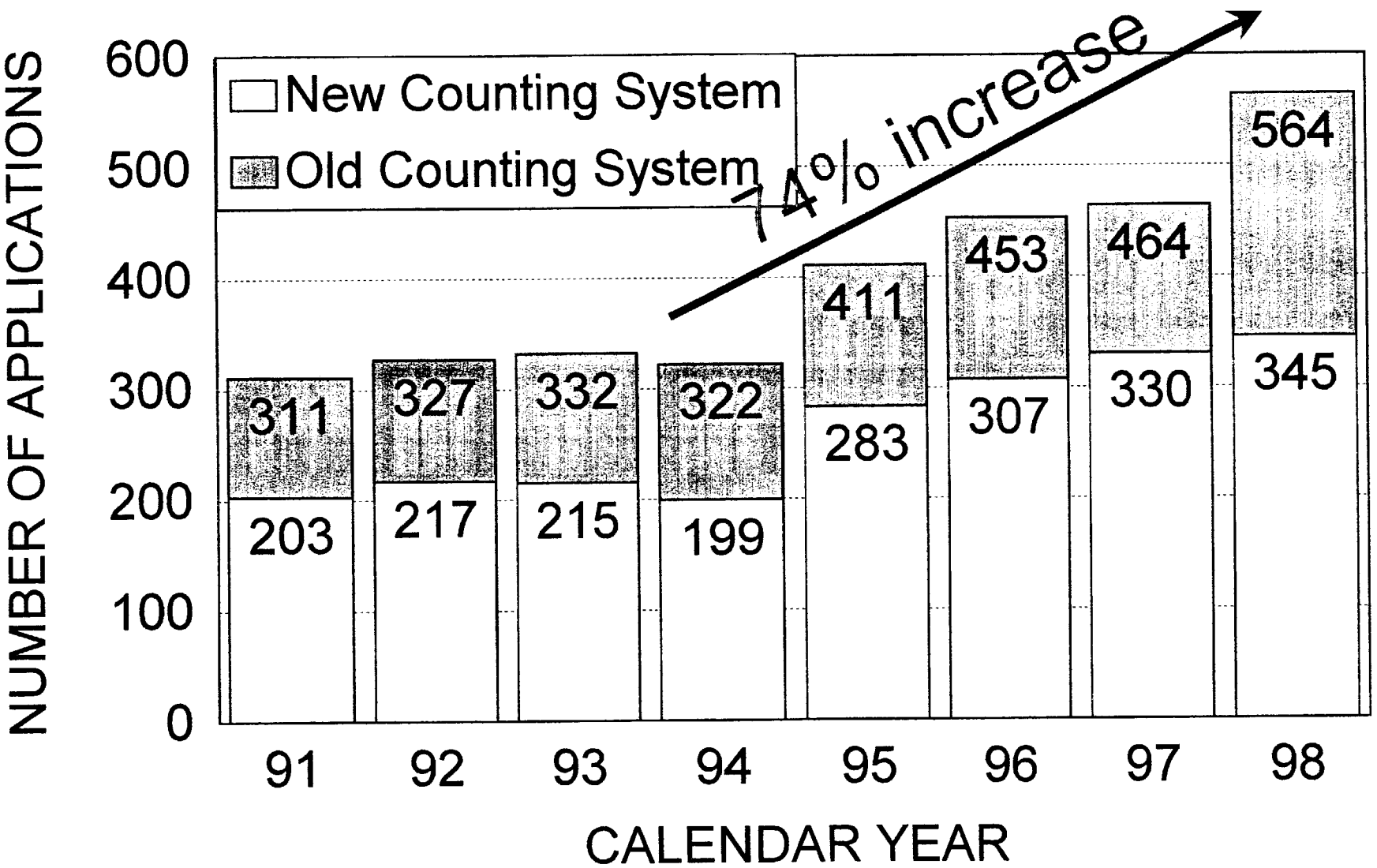
Issues and Challenges for the Year Ahead

- Recruitment & Retention
- Maximizing Review Performance
- Guidance to Industry
- Foster Electronic Submission & Review Environment
- Cope with Citizen Petitions & Lawsuits

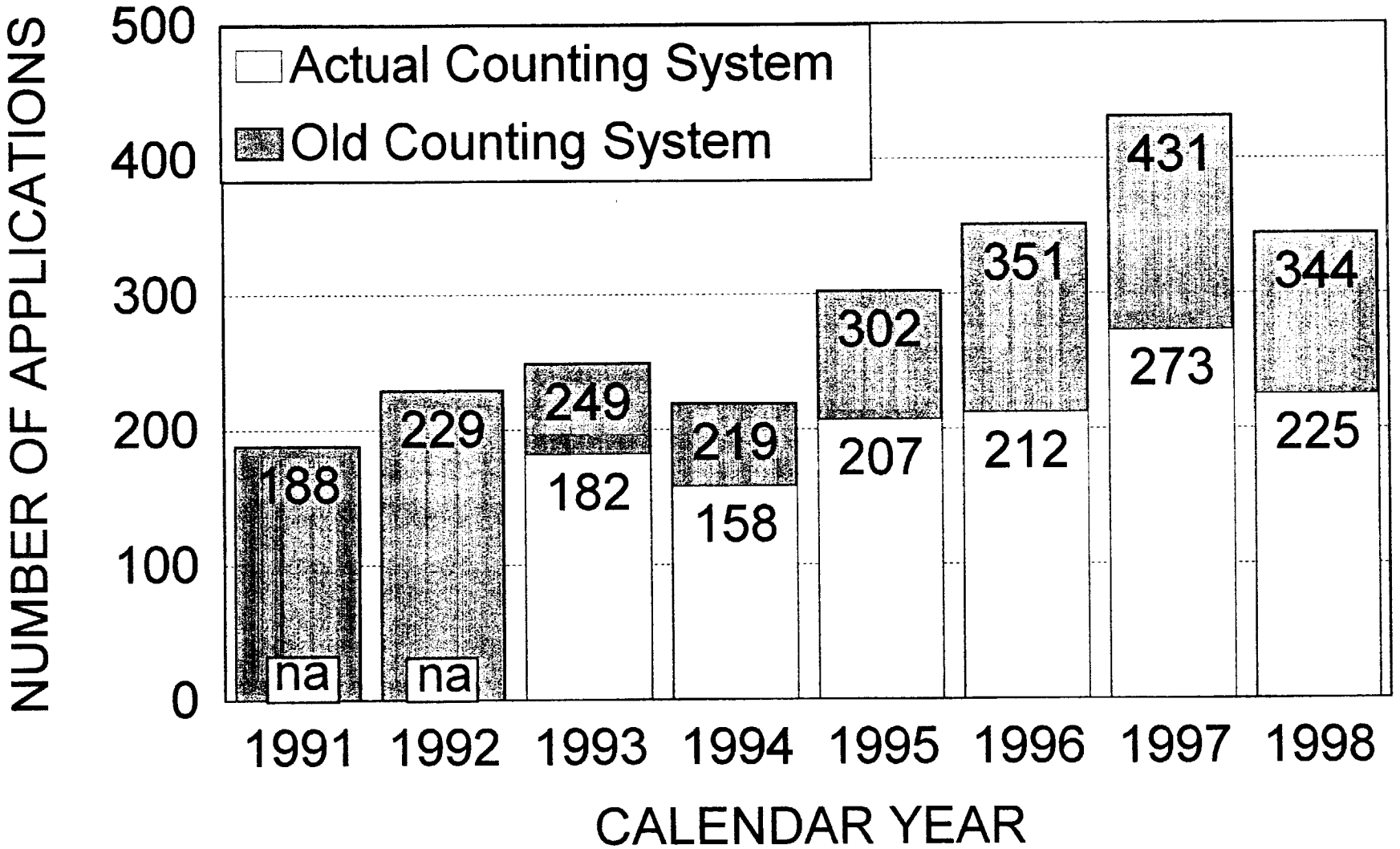
Office of Generic Drugs



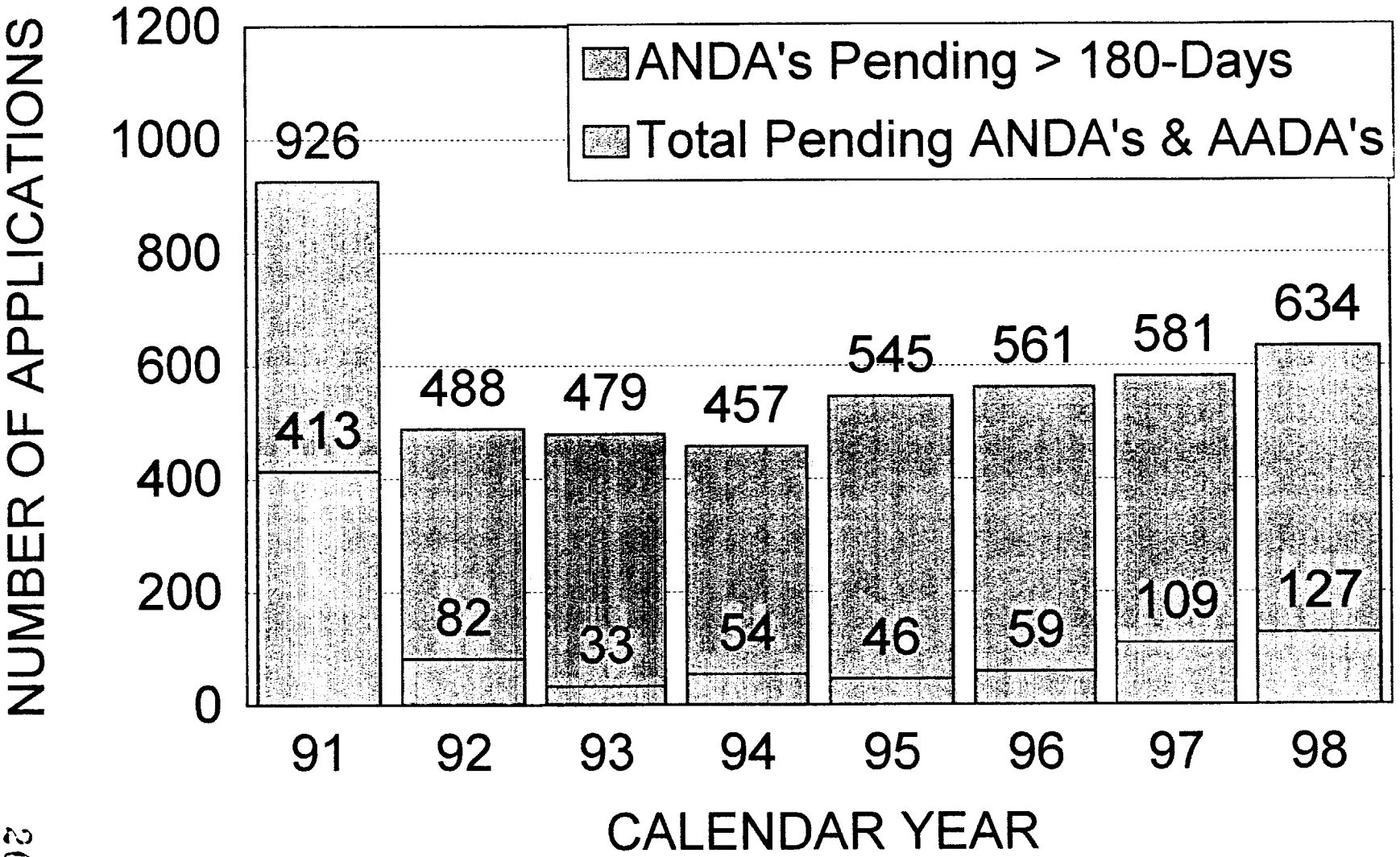
Calendar Year Receipts



Calendar Year Approvals



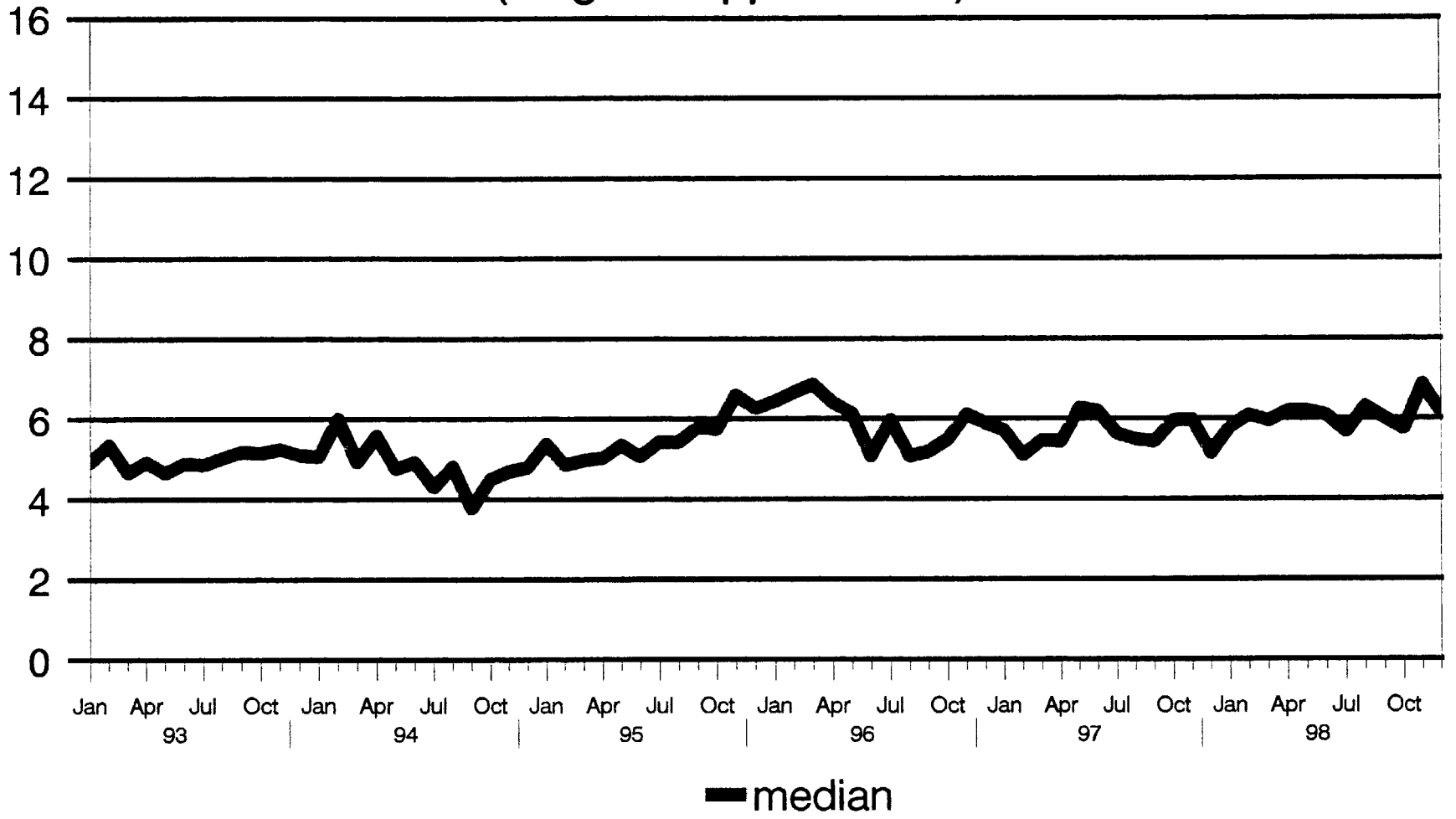
Monthly Average of Pending Applications



(Old Counting System)

Median ANDA Review Cycle (Months)

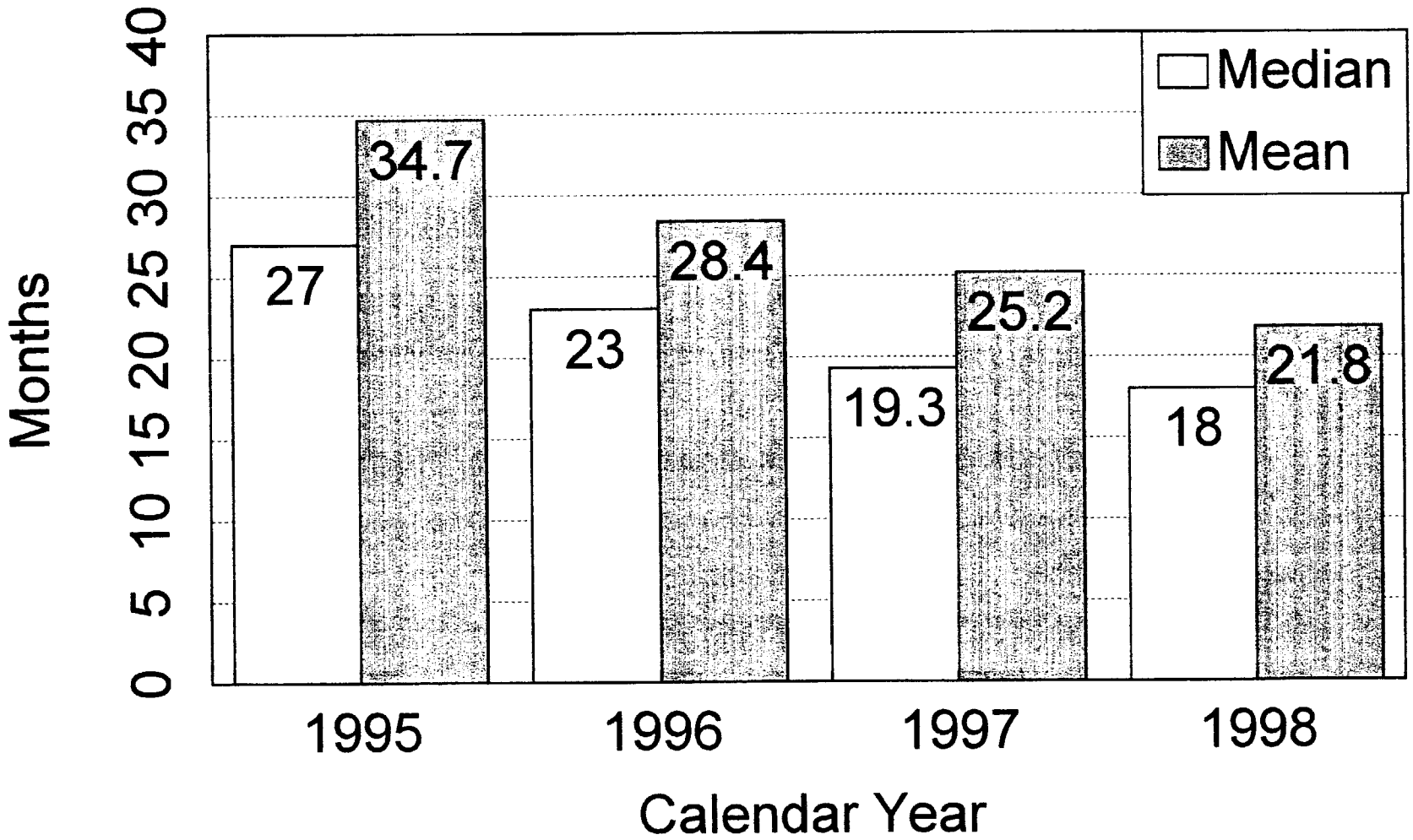
(Original Applications)



1-Times correspond to actual applications received . The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

2-In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are not reflected in the above chart.

Approval Times



Maximize Review Performance

- DMF Faxing Policy
- Variations in Drug Products Guidance
- Content and Format Revised Guidance
- FDAMA, Section 119 Guidance (Draft)

Guidance to Industry

- Mova/180-Day Exclusivity Proposal
- Pediatric Rule
- Major/Minor Determinations
- Inactive Ingredients
- Skin Irritation Studies
- "Complete Response Letter" Proposal
- Electronic Submissions

Electronic Submissions
- Receipts -

	1997	1998
BE:	9	38
CMC:	-	43
Participating:	-	24

(58 separate ANDA's)

Electronic Submissions
- Grace Period -

Current Grace Period: 45 days

As of April 1, 1999: 30 days

Citizen Petitions and Lawsuits

Product	Petition	Lawsuit
Cyclosporine	✓	✓
Paclitaxel	✓	
Phenytoin	✓	✓
Propofol	✓	✓
Ticlopidine	✓✓	✓
Verapamil	✓	